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Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,

This Document Relates to:

Debra Tinlin, et al. v. C. R. Bard, Inc., et al.
CV-16-00263-PHX-DGC

No. 2:15-MD-02641-DGC

DEFENDANTS' MOTION *IN LIMINE* NO. 2 TO EXCLUDE EVIDENCE OF FDA WARNING LETTER

(Assigned to the Honorable David G. Campbell)

(Oral Argument Requested)

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Bard respectfully re-urges its motion *in limine* (Doc. 9864) to exclude any reference, evidence, or argument concerning the July 13, 2015, FDA Warning Letter.[1]

ARGUMENT AND CITATION OF AUTHORITY

I. The FDA Warning Letter Should Be Excluded as Irrelevant in this Case.

The FDA Warning Letter has no relevance in this case for four reasons:

First, the Warning Letter has nothing at all to do with the Recovery® Filter that Mrs. Tinlin received. Indeed, the Warning Letter was issued ***nearly ten years*** after Bard ceased selling the Recovery Filter in September 2005, and ***more than ten years*** after Mrs. Tinlin received her Recovery Filter in May 2005. None of the topics in the Warning Letter address or concern the Recovery Filter. In particular, Topics 1 and 2 concern the Recovery® Cone retrieval system (***not*** the Recovery Filter), and Topics 4(b), 5, 6, 7, and 8 concern the Denali® Filter (Bard's ***seventh***-generation retrievable filter). Neither the Recovery Cone nor Denali Filter are at issue in this case. Similarly, Topic 4(a) concerns the filter cleaning process for the Simon Nitinol®, Eclipse®, and Denali Filters, and Plaintiffs have alleged no issue with the filter cleaning process in this case. Therefore, for the same reasons as in *Booker*, *Jones*, and *Hyde*, these topics are irrelevant here. (*See* Doc. 10258 at 6; *Booker* Trial Tr. at 1890:6-9 (D. Ariz. Mar. 27, 2018); Docs. 10805, 12736.)

Critically, unlike in *Booker*, *Jones*, and *Hyde*, Topic 3 does not address or concern Bard's complaint handling and MDR reporting processes relating to the Recovery Filter. The Court admitted the Warning Letter in redacted form in the first three bellwether trials in part because it found Topic 3 relevant to Bard's complaint handling and MDR reporting processes with respect to the G2®, G2®X, and Eclipse Filters at issue in those cases. (*See, e.g.*, *Booker* Trial. Tr. at 1888:21 to 1892:25 (permitting limited portions "of the G2 letter to be presented" because it concerned "handling and reporting of adverse events with respect to the G2 Filter").) Yet, not a single Recovery Filter complaint is addressed in Topic 3. Topic 3.a by definition concerns only the Denali Filter; Topic 3.b concerns the

[1] Counsel for Bard conferred with counsel for Plaintiffs and this motion is opposed.

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G2, G2® Express, Eclipse and Denali Filters; and Topic 3.c concerns various unidentified Bard IVC Filters[2] with allegations that Bard's complaint file documentation was deficient. But Plaintiffs have not alleged that Bard's handling of her internal complaint was deficient in any manner, nor that any alleged inadequacy in that documentation in any way caused or contributed to her claimed injuries. Therefore, these items are irrelevant.

Second, unlike in *Booker*, the Warning Letter is not relevant to rebut any "implication" at trial that FDA never took any action with respect to Bard's Recovery Filter. (*Id.* at 1888:21 to 1889:10.) This fact is beyond dispute: FDA never took enforcement action as to the Recovery Filter. The Warning Letter does not refute that fact.

Third, Plaintiffs lack any testimony that Mrs. Tinlin's implanting physician relies on MAUDE to make treatment decisions. Thus, like the Court found in *Booker*, any alleged failure by Bard to timely or accurately report complications to FDA could not have had any causative impact on Plaintiffs' claims or alleged injuries. (*Id.* at 1888:5-11.)

Fourth, the Warning Letter is not relevant to punitive damages because Bard's conduct addressed in the Letter did "not cause or contribute to the plaintiff's loss." *Henrikson v. Strapon*, 758 N.W.2d 205, 211 (Wis. 2008); *see also Kehl v. Economy Fire & Cas. Co.*, 433 N.W.2d 279, 280 (Wis. Ct. App. 1988) ("[P]laintiff [must] prove that he or she has suffered some actual damage as a result of the conduct."); (*Cf.* Doc. 12734 ("*Kehl* and *Henrikson* make clear that actions of a defendant are not admissible on punitive damages unless they caused or contributed to the plaintiff's loss.").)

Accordingly, the Warning Letter is simply not relevant in this Recovery Filter case, and should be excluded. *See* Fed. R. Evid. 401, 402; *see, e.g.*, *In re Seroquel Prod. Liab. Litig.*, No. 6:06MD1769-ORL-22DAB, 2009 WL 223140, at *5 (M.D. Fla. Jan. 30, 2009) (excluding Warning Letter as irrelevant where it did not at all involve the product at issue); *In re Viagra Prod. Liab. Litig.*, 658 F. Supp. 2d 950, 966–67 (D. Minn. 2009) (finding that three FDA letters regarding Viagra advertisements were irrelevant and

[2] Bard was only able to determine the model of filter received by one out of the 10 patients referenced in Topic 3.c, which was a G2 Filter.

inadmissible because two of the letters were issued after the plaintiff stopped using Viagra and there was no evidence the plaintiff saw the advertisements in the third).[3]

II. The FDA Warning Letter is Inadmissible Under Rule 403.

As demonstrated above, the FDA Warning Letter has no bearing on the issues to be tried. Its sole purpose in this case is so Plaintiffs can say that FDA issued a formal warning letter to Bard to inappropriately suggest that Bard did something wrong concerning the Recovery Filter. Since the FDA Warning Letter has no impact on Plaintiffs' actual claims in this case, and says nothing at all about the Recovery Filter, whatever probative value the Letter may provide is substantially outweighed by the real danger of unfair prejudice to Bard. The jury would be invited by Plaintiffs to believe that the Warning Letter somehow implicates the design or warnings associated with the Recovery Filter, even though nothing in the Letter suggests any such deficiencies.

Moreover, if Plaintiffs were allowed to introduce evidence regarding the Warning Letter, Bard would be forced to waste critical trial time putting such evidence into proper context when such evidence involves collateral questions not at issue in this case. The Warning Letter would become a substantial "side-show" in this matter, confusing and distracting the jury from the true issues to be decided in this case. Therefore, it should be excluded under Rule 403. *See, e.g.*, *Smith v. I-Flow Corp.*, No. 09 C 3908, 2011 WL 12627557, at *2 (N.D. Ill. June 15, 2011) ("[T]he FDA's December 2008 warning letter [] is inadmissible as irrelevant and under [Rule] 403 due to the potential for unfair prejudice that far outweighs any limited probative value the letter might have regarding the issues the jury will be called upon to decide."); *see also Ortho-McNeil-Janssen Pharm., Inc.* v. *State*, 432 S.W.3d 563, 580 (Ark. 2014) (FDA Warning Letter "more prejudicial than probative"); *Newman v. McNeil Consumer Healthcare*, No. 10 C 1541, 2013 WL 4460011, at *18 (N.D. Ill. Mar. 29, 2013) (Letter excluded as "highly prejudicial").

[3] Because "[t]he parties shall not repeat arguments previously made," (Docs. 11659 at 3; 11871 at 3), Bard does not include the various other arguments that were previously raised in its original motion *in limine* (Doc. 9864), but expressly preserves them for the record.

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CONCLUSION

For these reasons, Bard respectfully requests that the Court grant its Motion.

RESPECTFULLY SUBMITTED this 29th day of March, 2019.

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